CLAIMS

1. A purified rifaximin α, a polymorph of the antibiotic rifaximin, wherein said rifaximin α has a water content lower than 4.5%, and produces a powder X-ray diffractogram showing peaks at values of the diffraction angles 2θ of 6.6°; 7.4°; 7.9°; 8.8°; 10.5°; 11.1°; 11.8°; 12.9°; 17.6°; 18.5°; 19.7°; 21.0°; 21.4°; 22.1°.

2. The rifaximin α according to claim 1, wherein said water content is between 2.0% and 3.0%.

3. A purified rifaximin β, a polymorph of the antibiotic rifaximin wherein said rifaximin β has a water content higher than 4.5% and produces a powder X-ray diffractogram showing peaks at values of the diffraction angles 2θ of 5.4°; 6.4°; 7.0°; 7.8°; 9.0°; 10.4°; 13.1°, 14.4°; 17.1°; 17.9°; 18.3°; 20.9°

4. The rifaximin β according to claim 3, wherein said water content is between 5.0% and 6.0%.

5. A purified rifaximin γ, a polymorph of the antibiotic rifaximin wherein said rifaximin γ has a water content between 1.0% and 2.0% and produces a powder X-ray diffractogram showing a mainly amorphous profile and few significant peaks at values of diffraction angles 2θ of 5.0°; 7.1°; 8.4°.

6. A process for the production of rifaximins α, β and γ, comprising:

reacting a molar equivalent of rifamycin O with an excess of 2-amino-4-methylpyridine in a solvent mixture of water and ethyl alcohol in a volumetric ratio between 1:1 and 2:1, for a period of time between 2 and 8 hours, at a temperature between 40°C and 60°C,

treating the reaction mass at room temperature with a solution of

ascorbic acid in a mixture of water, ethyl alcohol and concentrated aqueous hydrochloric acid,

adjusting the pH of the reaction mass to pH 2.0 with a concentrated aqueous solution of hydrochloric acid,

filtering the suspension,

washing any resulting solid with the water/ethyl alcohol solvent mixture to obtain raw rifaximin,

purifying the raw rifaximin by dissolving it in ethyl alcohol at a temperature between 45°C and 65°C,

precipitating the raw rifaximin by adding water and by lowering the temperature of the suspension to between 0°C to 50°C under stirring for a period of time between 4 and 36 hours,

filtering the suspension,

washing the resulting solid with water, and

drying it under vacuum or under conditions of normal pressure, with or without a drying agent, at a temperature between room temperature and 105°C, for a period of time between 2 and 72 hours.

7. The process according to claim 6, wherein said 2-amino-4-methylpyridine is from 2.0 to 3.5 molar equivalents.

8. The process according to claim 6, wherein said water added to precipitate the raw rifaximin is in a weight amount between 15% and 70% with respect to the weight amount of ethyl alcohol used for the dissolution.

9. The process according to claim 6 for the production of rifaximin α, wherein after the addition of water to the raw rifaximin, the temperature is lowered to a value between 28°C and 32°C in order to cause the beginning of

the crystallization,

stirring the resulting suspension at a temperature between 40°C and 50°C for a period of time between 6 and 24 hours,

cooling the suspension to 0°C for a period of time between 15 minutes and one hour,

filtering the suspension, washing the resulting solid with water, and

drying the washed solid until a water content lower than 4.5% is reached.

10. The process according to claim 9, wherein said water content is between 2.0% and 3.0%.

11. The process according to claim 6 for the production of rifaximin β,

wherein after the addition of water to the raw rifaximin, the temperature is lowered to a value between 28°C and 32°C in order to cause the beginning of the crystallization,

stirring the resulting suspension at a temperature between 40°C and 50°C for a period of time between 6 and 24 hours,

cooling the suspension to 0°C for a period of time between 15 minutes and one hour,

filtering the suspension, washing the resulting solid with water, and

drying the washed solid until a water content higher than 4.5% is reached.

12. The process according to claim 11, wherein said water content is between 5.0% and 6.0%.

13. The process according to claim 6 for the production of rifaximin γ, wherein after the addition of water to the raw rifaximin, the temperature is

lowered to a value between 28°C and 32°C in order to cause the beginning of the crystallization,

cooling the suspension to 0°C for a period of time between 6 and 24 hours,

filtering the suspension, washing the resulting solid with water and

drying the washed solid until a water content between 1.0% and 2.0% is reached.

14. A process for the production of rifaximin α, comprising

suspending rifaximin γ in a solvent mixture of ethyl alcohol/water in a volumetric ratio of 7:3,

heating the suspension at a temperature between 38°C and 50°C, under stirring, for a period of time between 6 and 36 hours,

filtering the suspension,

washing the resulting solid with water, and

drying the washed solid until a water content lower than 4.5% is reached.

15. The process according to claim 14, wherein said water content is between 2.0% and 3.0%.

16. A process for the production of rifaximin β, comprising

suspending rifaximin γ in a solvent mixture of ethyl alcohol/water in a volumetric ratio of 7:3,

heating the suspension at a temperature between 38°C and 50°C, under stirring, for a period of time between 6 and 36 hours,

filtering the suspension,

washing the resulting solid with water, and

drying the washed solid until a water content higher than 4.5% is reached.

17. The process according to claim 16, wherein said water content is between 5.0% and 6.0%.

18. A process for the production of rifaximin γ, comprising

dissolving rifaximin α or β in ethyl alcohol at a temperature between 50°C and 60°C,

adding demineralized water until an ethyl alcohol/water volumetric ratio equal to 7:3 is reached,

cooling the solution to 30°C under strong stirring,

further cooling the resulting suspension to 0°C for a period of time between 6 and 24 hours,

filtering said suspension,

washing the resulting solid with water, and

drying the solid until a water content lower than 2.0% is reached.

19. A process for the production of rifaximin β, comprising keeping rifaximin α in an ambient environment having a relative humidity higher than 50% for a period of time between 12 and 48 hours until said rifaximin α is converted into rifaximin β.

20. A process for the production of rifaximin α, comprising drying rifaximin β under atmospheric pressure, or under vacuum, or in the presence of a drying agent, at a temperature between the room temperature and 105°C, for a period of time between 2 and 72 hours until said rifaximin β is converted into rifaximin α.

21. A composition comprising a predetermined amount of rifaximin α, rifaximin β or rifaximin γ in combination with excipients suitable for oral administration.

22. The composition according to claim 21, wherein said excipients are

suitable for the production of coated and uncoated tablets, hard and soft gelatin capsules, sugar-coated pills, lozenges, wafer sheets, pellets and/or powders.

23. A composition comprising a predetermined amount of rifaximin α, rifaximin β or rifaximin γ in combination with excipients suitable for topical administration.

24. The composition according to claim 23, wherein said excipients are suitable for the production of ointments, pomades, creams, gels and lotions.

25. A composition comprising predetermined amounts of rifaximin α, rifaximin β, or rifaximin γ or any combination thereof, in combination with pharmaceutically acceptable excipients.

26. A method for treating a patient in need of antibiotic therapy, comprising administering the composition according to claim 25 to said patient.

27. The method according to claim 26, wherein said composition is administered orally.

28. The method according to claim 26, wherein said composition is administered topically.

29. A composition comprising the rifaximin α according to claim 1 in combination with pharmaceutically acceptable excipients.

30. A composition comprising the rifaximin β according to claim 3 in combination with pharmaceutically acceptable excipients.

31. A composition comprising the rifaximin γ according to claim 5 in combination with pharmaceutically acceptable excipients.